ANALYSIS OF AGENDA ITEMS IN PREPARATION FOR THE 16th SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOOD (CCCF16)

18 to 21 April 2023 (physical plenary meeting)

26 April 2023 (virtual report adoption)

Agenda Item 5: Maximum Levels for Lead in Certain Food Categories (At Step 4 and 7)

OBJECTIVES

This document offers a review and analysis of the agenda items planned for discussion at the 16th session of the **Codex Committee on contaminants in Foods (CCCF16)**, scheduled to take place face to face from 18 to 21 April 2023 (physical plenary meeting) and 26 April 2023 (virtual report adoption). This document is intended for possible use by the Codex communities of practice, promoted by GFoRSS and PARERA, as part of their contribution to enhancing awareness and supporting effective participation in international food standard setting meetings (Codex meetings) by representatives from members and observers.

The analysis provided in this document offers a factual review of agenda items, their background and a discussion of some considerations. This analysis is indicative in nature and does not represent an official position of the organizations mentioned above (PARERA and GFoRSS), their membership or their management. It provides a synthesis and analysis of the work currently under discussion by the CCCF, which may be useful for delegations from Arab countries to prepare their positions considering the needs and specificity of the region and the potential impact of the proposed food standards. This analysis is prepared as part of the **Codex Initiative for the Arab Region: Arab Codex Initiative**, implemented by PARERA and GFoRSS, hosted and coordinated by the Arab Industrial Development, Standardization and Mining Organization (AIDSMO) and funded by the US Codex Office, US Department of Agriculture.

**It is important to note that experts – members of the Expert Working Group (EWG) – do not represent the organizations and / or jurisdictions to which they are affiliated. The selection and participation in the EWG proceedings is based on each expert's own credentials and experience which should not be misconstrued as the country's / delegation's / organization's position to which they belong.*

Agenda Item 5: Maximum levels for lead in certain food categories (at Step 4 and 7)

Documents

- CX/CF 23/16/5 and CX/CF 23/16/5-Add.1

Background

Lead is a naturally occurring toxic metal found in the environment and in different products. Its widespread use has resulted in extensive environmental contamination, human exposure and significant public health problems in many parts of the world. International organizations include the reduction of risks of exposure to lead among the priority themes in terms of environmental health.

Considering the conclusions of JECFA73 (2011) about dietary lead exposure, CCCF started working since its 6th session on the revision of Maximum Levels (MLs) for lead established in the General Standard for Contaminants in Food and Feed (CXS 193-1995) to reduce dietary exposure to lead.

The key decisions reached by the committee are presented below:

- **At the CCCF11 (2017),** The Committee agreed to expand the work on Lead beyond the food categories listed in CXS 193, with the consideration of new Maximum Levels (MLs) for a range of food commodities.
- Since then, an Electronic Working Group (EWG) led by Brazil has been working on proposals for new MLs for lead in selected food commodities.
- **At the CCCF12 (2018) and CCCF13 (2019)**, the committee discussed the criteria to select new food categories for ML elaboration, considering international trade and potential exposure. CCCF13 agreed to focus on **MLs proposals for lead in food for infants and young children** (except those for which MLs have already been established in CXS 193, spices and aromatic herbs; eggs and sugars and confectionery, excluding cocoa.
- The EWG established at CCCF13 worked on lead data extracted from the GEMS/Food Database considering results from 2008 – 2019. MLs were proposed for eggs, preserved eggs, fresh and dried culinary herbs and spices (fruits and berries; fresh and dried rhizomes, bulbs and roots; bark; floral parts; seed).
- **At the CCCF14** (**May 2021)**, CCCF agreed to:
  i. clarify that the MLs for **fruit juices and grape juices** in CXS 193 also apply them to infants and young children. These MLs were adopted at CAC44;
  ii. Discontinue work on an ML for **herbal teas, yoghurt, cheese and milk-based** products for infants and young children;
- **At the CCCF15** (**2022)**, CCCF agreed to:
  i. **Discontinue work on fresh eggs** its low relevance for international trade and the low occurrence levels observed;
  ii. **Discontinue work on ML for dried garlic** given that there is already an ML of 0.1 mg/kg for fresh garlic on the GSTCFF
  iii. **Discontinue work on molasses** as there was not sufficient data to establish a ML.
  iv. Recommend the adoption by CAC45 the following MLs at Step 5/8
    - Cereal-based foods for infants and young children at **0.02 mg/kg**;
    - White and refined sugar, corn and maple syrups and honey at **0.1 mg/kg**
    - Sugar-based candies at **0.1 mg/kg**,
  v. To consider a separate ML for brown and raw sugar due to the high-value of these commodities in international trade and because it is likely to contain more lead than white or refined sugar

vi. Forward the ML for lead at 0.02 mg/kg at Step 5 for ready-to-eat meals for infants and young children and further consideration by the EWG as per the possible exclusion of certain foods that may not be able to achieve this ML for consideration at CCCF16 (2023).

vii. Re-establish the EWG, led by Brazil, to consider MLs for **ready-to-eat meals for infants and young children (exclusion of certain foods) and brown and raw cane sugars** based on data currently available in GEMS/Food for consideration by **CCCF16 (2023)** and MLs for **culinary herbs** (fresh/dried) and **spices** (dried) following a JECFA call for data in 2022 for consideration by **CCCF17 (2024).**

At the CCCF16, delegates will discuss MLs for sugar (soft brown, raw and non-centrifuged), and for ready-to-eat meals for infants and young children (exclusion of certain foods).

For soft brown sugar, raw sugar and non-centrifuged sugar (including Panela and Mascavo): delegates will discuss EWG's proposals which is a single ML at 0.15 mg/kg.

For ready-to-eat meals for infants (up to 12 months) and young children (12 to 36 months), delegates will consider the following proposals:

- to establish a single **ML of 0.02 mg/kg** for the whole category of ready-to-eat meals for infants and young children as proposed by CCCF15 and adopted at Step 5 by CAC44 in 2022
- As proposed by the EWG, to consider
  - Adoption of **a single ML of 0.03 mg/kg** for the entire food category, slightly higher than the one that was advanced at Step 5 by CCCF15, or
  - Adoption of the single **ML of 0.02 mg/kg** with the exclusion of products containing **cereals**.

Analysis

18 countries and 3 organizations participated to the EWG's work led by Brazil, to consider MLs for ready-to-eat meals for infants and young children (exclusion of certain foods) and brown and raw cane sugars based on data currently available on GEMS/Food for consideration by CCCF16 (2023).

Analysis of the methodology followed by the EWG

No new call for data was conducted to consider maximum levels (MLs) by CCCF16:

The EWG analysed data extracted in 2021 by the WHO Administrator of GEMS/Food, covering data from 2011 to 2021 of lead levels in sugars and ready-to-eat meals for infants and young children.

The EWG used different scenarios within the analysis of dataset and decided to derive a second dataset resulting from data treatment based on the steps described below:

- **In the first step by removing results of non-detected (ND) samples** by using the UB approach in order to assure that the MLs are not established below the limit of quantification (LOQ)
  - It was observed that many data were classified as non-detected (ND), but the results were obtained with methods with high level of quantification (LOQ) values;
  - To use the **upper bound approach** in which the results below level of detection (LOD) were replaced **by the numerical value of the LOD** and those **below the LOQ** were replaced by the **value reported as LOQ**.
- **In the second step by excluding results that could contribute to distortion in distribution, using the following approach:**
  - For ready-to-eat meals for infants and young children, data obtained with methods using LOQs higher than the proposed ML of 0.02 mg/kg advanced at step 5 CCCF15, were excluded, in accordance with the recommendation stated in the document "Guidance on data analysis for the development of maximum levels and improved data collection" (under discussion by CCCF);

- For the brown and raw sugars Data: EWG decided to exclude Data above P95 values for sugars as no LMs were established for these products by CCCF and no guidance are mentioned related to this case in the mentioned document.

The EWG proposed the classification of the different sugar categories identified in the submitted data to GEMS/Food i.e."brown sugar", "soft brown sugar", "demerara" , "raw sugars" panela, mascavo and tapon sugar into the three distinct following categories:

- **Brown sugar:** includes soft brown sugars
- **Raw cane sugar**: which includes Demerara
- **Non-centrifuged sugars:** which includes Panela

The EWG employed a substitution method relying on the Upper Bound (UB) approach to derive MLs different based on the following rationale:

- MLs for lead in sugars (brown, raw and non-centrifuged) and ready-to-eat meals for infants and young children are being proposed considering the approach "As Low as Reasonably Achievable" ALARA, with **rejection rates less than 5%.**
- Considering that more than 27% of lead in sugar and more than 60% of lead in ready-to-eat meals for infants and young children is left-censored, it was considered more appropriate to discuss MLs for these food categories using the UB approach instead the middle bound (MB) approach followed the previous year.
- For ready to-eat meals for infants and young children it was observed that P95 values in this second scenario were not modified if Middle-bound or Upper Bound (UB) approach were used, with P95 of **0.023 mg/kg** in both cases (data not shown). The EWG decided then to use only the UB approach.

The EWG adopted a specific identification and classification of ready-to-eat meals for infants and young children (RTE)

- All data reported on the fields "food category" as "**food for infants and small children**" and "food name" as "**Ready-to-eat meal for infants and young children**" were considered. Results reported in other food categories or under other food names were not considered.
- Due to the lack of the data related to the composition of food in the Database, **RTE food containing cereals** referred to all multi-ingredient products that contain cereals or root vegetables, with no consideration of the percentage.

Analysis of the hypothetical's effect of the proposed MLs for lead:

The EWG made recommendations for MLs of Lead in the studied commodities as follows:

(1) For the sugar categories considered: two key parameters were analysed, the sample rejection rate (SR) and the resulting reduction of exposure to lead or intake reduction (IR), aiming for the highest possible reduction of exposure, while maintaining a SR below 5%.

The application of the proposed ML of 0.15 mg/kg led to the following hypothetical outcome using the data available

Sugar Category	Proposed ML	Sample rejection "SR"/intake reduction "IR" rates with all data (%)	Sample rejection "SR"/intake reduction "IR" rates after high LOQs exclusion (%)
Brown sugar	0.15 mg/kg	SR 3.3 (90 data)/ IR 33	SR 3.7 (81 data)/ IR13.1
raw cane sugars	0.15 mg/kg	SR 2.8 (250 data)/IR 30.1	SR 1.3 (227 data)/IR 10.9
non centrifuged sugar (panela)	0.15 mg/kg	SR 0 (76 data)/ IR 0	SR 0 (75 data)/ IR 0
All **sugar products**	0.15 mg/kg	SR 4.3 (416 data)/IR 21.7	SR 1.6 (369 data)/ IR 7.1

Therefore, the EWG is recommending:

1. **A single ML equivalent to 0.15mg/kg applicable to all less refined sugar products given their similarities (therefore avoiding the reliance on product classification)**

This ML is slightly higher level than the ML adopted by CCCF15/CAC45 for lead in white and refined sugars of 0.1 mg/kg.

2. **For ready-to-eat meals for infants and young children:**

The EWG considered the impact of the proposed ML on the targeted food categories (ready-to-eat meals for infants and young children), with a particular attention to those containing cereals:

The following table summarizes this analysis

Food Categories	Proposed ML	Sample rejection rate with all data (%)	Sample rejection rate after high LOQs exclusion (%)
Ready-to-eat meals	0.02 mg/kg	13	5.3
	0.03 mg/kg	7.1	1.8
Ready-to-eat meals containing roots	0.02 mg/kg	8.2	4.8
	0.03 mg/kg	0.5	0.6
Ready-to-eat meals containing cereals	0.02 mg/kg	13.9	11.7
	0.03 mg/kg	9.5	5.5

Using the second scenario for data handling i.e., removing data with high LOQs, lead acceptable rejection rates (less than 5%) for all categories except Ready to eat meals for children and infant containing cereals.

It seems that products containing cereals would have a higher level of contamination with lead resulting in higher reduction rates.

The EWG recommended therefore the consideration of the two options:

- **Adoption of a_single ML of 0.03 mg/kg for the entire food category, slightly higher than the one that was advanced at Step 5 by CCCF15, or**
- **Adoption of the single ML of 0.02 mg/kg with the exclusion of products containing cereals.**

Conclusion and Considerations for the Region

The EWG addressed the task requested by CCCF15 and made the recommendations needed for Lead in the targeted commodities:

Arab Codex delegations may support the adoption of

- **Single ML for lead equivalent of 0.15mg/kg applicable to all raw or less refined sugar products**
- **Single ML for Lead of 0.02 mg/kg in Ready-to-eat meals for infants and young children** (the whole category including those with cereals) knowing that the same LM was already adopted at the step 5/8 by CAC45 for cereal-based foods for infants and young children.

The general recommendations to:

- generate occurrence data for contaminants in food products such as lead and which would support submission to the GEMS Food data base
- ascertain the achievability of the proposed MLs through on-going food monitoring activities
- ascertain consultation with the food production sector on the possible impacts of the proposed MLs, including the availability and price of products are maintained.